

K073654

Premarket Notification Special 510(k)  
Blackstone Medical, Inc.  
Blackstone™ Ascent® POCT System  
Parallel Rod Connector (System Modification)  
**Confidential**

**510(K) SUMMARY**

JAN 24 2008

**Name of Firm:** Blackstone Medical, Inc.  
1211 Hamburg Turnpike  
Wayne, NJ 07470

**510(k) Contact:** Whitney Törning, Senior Director of Regulatory Affairs &  
Quality Assurance

**Submitter:** Martin Sprunck, Regulatory Affairs Manager

**Trade Name:** Blackstone™ Ascent® Posterior Occipital Cervico-  
Thoracic (POCT) System

**Common Name:** Rod and screw spinal instrumentation

**Device Classification:** Class II

**Classification Product Code:** KWP – 888.3050 – Spinal Interlaminar Fixation Orthosis

**Substantially Equivalent Devices:**

Blackstone™ Posterior Cervical System (K030197 SE 6-12-03)  
Blackstone™ Ascent POCT System Lateral Offset Adaptors (K040034 SE 2-11-04)  
Blackstone™ Ascent POCT System 5.5mm/3.0mm Single Axial Connector  
(K042100 SE 9-20-04)  
DePuy Spine Summit and Mountaineer OCT Spinal Systems (K042508 SE 10-7-04)

**Device Description:**

Description: The Blackstone Ascent POCT System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The Ascent POCT System consists of an assortment of rods, setscrews, cross connectors, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws, and Songer Cables.

Levels of Use: When used in the occipito-cervico-thoracic spine, the Blackstone Posterior Cervical System may be used from the occiput to T3.

**Indications:** When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Blackstone Ascent POCT System is indicated for:

- a) degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
- b) spondylolisthesis;
- c) fracture/dislocation;
- d) spinal stenosis;
- e) atlanto-axial fracture with instability;
- f) occipito-cervical dislocation;
- g) tumors;
- h) revision of previous cervical spine surgery

The occipital bone screws are limited to occipital fixation only. The use of the multi-axial screws is limited to placement in the upper thoracic spine (T1-T3) for the treatment of thoracic conditions only. They are not intended to be placed in the cervical spine. The lateral offset adapter is indicated for use in the upper thoracic spine (T1-T3). The hooks are intended to be placed from C1 to T3. The Songer Cable (titanium) System to be used with the Blackstone Ascent POCT System allows for wire/cable attachment to the posterior cervical spine.

The Blackstone Ascent POCT System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial Connector or the Blackstone Ascent Parallel Rod Connector.

**Basis of Substantial Equivalence:**

The additional Blackstone™ Ascent Parallel Rod Connector is substantially equivalent to the identified predicate systems, which have been cleared by FDA for the purpose of building a spinal implant construct in the occipito-cervico-thoracic spine.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 24 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Blackstone Medical, Inc.  
% Ms. Whitney Törning  
Senior Director of Regulatory Affairs and Quality Assurance  
1211 Hamburg Turnpike, Suite 300  
Wayne, NJ 07470

Re: K073654  
Trade/Device Name: Ascent® Posterior Occipital Cervico-Thoracic (POCT) System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: KWP  
Dated: December 21, 2007  
Received: December 26, 2007

Dear Ms. Törning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Whitney Törning

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Blackstone™ Ascent Posterior Occipital Cervical Thoracic System (POCT) System

### Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Blackstone Ascent POCT System is indicated for:

- a) degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
- b) spondylolisthesis;
- c) fracture/dislocation;
- d) spinal stenosis;
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The Blackstone Ascent POCT System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial Connector or the Blackstone Ascent Parallel Rod Connector.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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